Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12880

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

COMPLAINT / INJURY REPORT

1. COMPLAINT NUMBER: CIN-8008 12880
2. DATE OF COMPLAINT (Month / Day / Year): 4/27/98

3. FORM OF COMPLAINT
a. (1) [X] TELEPHONE (2) [ ] LETTER (3) [ ] VISIT

4. SOURCE OF COMPLAINT
a. (1) [X] CONSUMER (3) [ ] TRADE SOURCE (2) [ ] GOVERNMENT (4) [ ] OTHER
[ ] L [ ] S [ ] F (Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION
a. NAME AND ADDRESS (Include ZIP Code): [redacted]
b. AREA CODE AND TELEPHONE NUMBER
HOME [redacted]
WORK ([redacted]

6. COMPLAINT OR INJURY
a. DESCRIPTION OF COMPLAINT / INJURY
Mr. [redacted] is concerned that the referenced adet caused him to develop GERD (acid reflux disease). Mr. [redacted] used the adet only occasionally between last fall & 3/98. After 2 weeks he stopped taking the adet because he was having chest pains. 3 days later he developed severe chest pain & was diagnosed (see Rmks)

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
(1) [X] NO (2) [ ] YES
(If "Yes" Explain in Remarks)

7. INJURY OR ILLNESS RESULTED
(1) [ ] NO
(2) [X] YES *
*(If "yes" complete items a through d)

a. EIB (HFC - 161) NOTIFIED
(1) [X] NO
(2) [ ] YES
DATE: _____

b. TYPE SYMPTOMS — ONSET (HR.)
(1) [ ] VOMITING
(2) [ ] NAUSEA
(3) [ ] DIARRHEA
(4) [ ] FEVER
(5) [ ] SKIN/EYE IRR.
(6) [ ] HEADACHE
(7) [X] OTHER see Ga

c. ATTENDING HEALTH PROFESSIONAL?
(1) [ ] NO (2) [X] YES
(If "Yes" give name, address, and phone number)
[redacted]

d. HOSPITALIZATION REQUIRED?
(1) [X] NO (2) [ ] YES
(If "Yes" give name, address, phone number and dates)

RECEIVED MAY 05 1998 FDA

8. PRODUCT AND LABELING
a. BRAND NAME: Metabolife
b. PRODUCT NAME: Metabolife 356
c. SIZE AND PACKAGE TYPE: 90 capsul plastic btl
d. NAME AND LOCATION OF STORE WHERE PURCHASED: mail order
e. PACKAGE CODE / SERIAL NUMBER / ETC.: G723
EXP. / USE BY DATE: 07/00
f. DATE PURCHASED: 0/a 11/97
g. PRODUCT USED (If "Yes" enter date) (1) [ ] NO (2) [X] YES Date:
h. AMT. REMAINING: 2 1/2 btl.

9. MANUFACTURER / DISTRIBUTOR OF PRODUCT
a. HOME DISTRICT: Den
b. C.F. NO.: 1717927
c. NAME AND LOCATION OF FIRM (Include ZIP Code): Metabolife Int. Inc. 5070 Santa Fe St. (619) 490-5222 San Diego, Ca 92109 (See Block 13)
d. IMPORT PRODUCT (1) [X] NO (2) [ ] YES

10. EVALUATION AND DISPOSITION
a. PROBLEM KEY WORD
(1) CODE: R
(2) DESCRIPTION: Chest pain

b. EVALUATION
(1) [ ] NOT AN FDA OBLIGATION
(2) [ ] OBLIGATION, NO VIOLATION
(3) [X] FDA ACTION INDICATED
(4) [ ] INSUFFICIENT INFORMATION UNABLE TO EVALUATE

b. DISPOSITION
(1) [ ] IMMEDIATE FOLLOW-UP
(2) [ ] F / U NEXT EI
(3) [ ] CLOSED WITHOUT FURTHER INVESTIGATION
(4) [ ] REFERRED TO OTHER FEDERAL AGENCY (Closes File)
(5) [ ] REFERRED TO STATE / LOCAL AGENCY (Closes File)
(6) [X] REFERRED TO OTHER FDA DEN DISTRICT
(7) [ ] REFERRED TO OCI

11. PRODUCT CODE: 54FCT09

12. INFORMATION COPIES TO:
[ ] HFM-660 [ ] HFZ-343
[ ] HFD-730 [X] HFC-161
[ ] HFV-210 [X] HFS-635
[ ] OTHER _____

13. REMARKS w/GERD. Mr. [redacted] never had any similar problems or symptoms in the past. He was not taking any other dietary supplements or prescription medications. 4/28/98 [redacted] (Pres. Metabolife) no similar complaints. Mfg. Chemmex Co Colorado Springs, Co 1-800-777-7161

14. NAME AND TITLE OF DISPOSITION OFFICIAL: David C Rolle PDM

15. DATE: 4/28/97

FORM FDA 2516 (1/96)

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Adverse Reaction Information Form A

Complaint Number: CIN-8008 Investigator: D. Radke

Consumer Information

Date of Report: 4/22/99 (MM/DD/YY)

Initial Report Source: ☒ORA Consumer Injury
☒Telephone ☐Correspondence ☐MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted] Gender: ☐F ☒M Age: 30

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other _____ ☐9-Unknown

Information on Adverse Reaction

Date of Adverse Reaction: 4/2/99
Previous Reaction to Product Type: ☐Yes ☒No

Give the site of consumption/ingestion (e.g. (home) restaurant, office):

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): Chest pain 17 days after starting daily use & 3 days after sporadic use.
How long did the symptoms last? Still has
Give the circumstances of exposure (e.g., dose, route of exposure, frequency, etc.). 3 tablets per day by mouth

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: None

Did event abate after use of suspected product stopped or dose reduced: ☒Yes ☒No ☐Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☒Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No
Give health care provider's name, address and telephone number: MD. [redacted]

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist
☐Other (specify) _____

What medical tests were performed and what were the results? Acid Reflux Disease

What was the medical diagnosis?
What treatment(s) was given (e.g., drugs, other)? Given prilosec

Were there any preexisting condition(s)/treatment(s)?
(If YES, list them including allergies, and chronic diseases): ☐Yes ☒No

Product Category

1. Adverse reaction to:
   ☐Medical Food (under medical supervision) ☐Infant Formula
   ☒Dietary Supplement (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe, amino acids, extracts from animal glands, garlic extract, fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients)
   ☐Other (traditional food) _____

Other Product Problems

2. ☐Foreign Object (specify): _____
3. ☐Other (specify): _____